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APPLICATION NO.	FIL	ING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/955,656	09	9/18/2001	Charles A. Nicolette	GZ 2096.00	1157
30089	7590	09/29/2003			
		RATION C/O M	WN, EXAMINER		
& ENERSEN MCCUTCHEN, DOYLE, BRÓWN & ENERSEN, LLP THREE EMBARCADERO CENTER				CHAKRABARTI, ARUN K	
SAN FRAN				ART UNIT	PAPER NUMBER
	,			1634	

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

Applicant(s)

09/955,656

Nicolette

Examiner

Arun Chakrabarti

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• •	rs on the cover sheet with the correspondence address			
Period for Reply	TTTO EVENE A MONTHUOLEDOM			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SE THE MAILING DATE OF THIS COMMUNICATION.	ET TO EXPIRE3 MONTH(S) FROM			
- Extensions of time may be available under the provisions of 37 CFR 1.136 (a).	In no event, however, may a reply be timely filed after SIX (6) MONTHS from the			
mailing date of this communication.  If the period for reply specified above is less than thirty (30) days, a reply within				
<ul> <li>If NO period for reply is specified above, the maximum statutory period will app</li> <li>Failure to reply within the set or extended period for reply will, by statute, caus-</li> </ul>				
<ul> <li>Any reply received by the Office later than three months after the mailing date earned patent term adjustment. See 37 CFR 1,704(b).</li> </ul>	of this communication, even if timely filed, may reduce any			
Status				
1) X Responsive to communication(s) filed on Sep 18,	. 2001			
2a) ☐ This action is <b>FINAL</b> . 2b) ☒ This a	action is non-final.			
3) Since this application is in condition for allowance closed in accordance with the practice under Exp	e except for formal matters, prosecution as to the merits is parte Quayle, 1935 C.D. 11; 453 O.G. 213.			
Disposition of Claims				
4) X Claim(s) <u>1-10</u>	is/are pending in the application.			
4a) Of the above, claim(s)	is/are withdrawn from consideration.			
5)	is/are allowed.			
6) 💢 Claim(s) <u>1-10</u>	is/are rejected.			
7)	is/are objected to.			
8) Claims	are subject to restriction and/or election requirement.			
Application Papers				
9) $\square$ The specification is objected to by the Examiner.	•			
10) The drawing(s) filed on is/a	re a) $\square$ accepted or b) $\square$ objected to by the Examiner.			
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) The proposed drawing correction filed on	is: a) $\square$ approved b) $\square$ disapproved by the Examiner.			
If approved, corrected drawings are required in repl	y to this Office action.			
12) The oath or declaration is objected to by the Example 12.	miner.			
Priority under 35 U.S.C. §§ 119 and 120				
13) Acknowledgement is made of a claim for foreign	priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) ☐ All b) ☐ Some* c) ☐ None of:				
1. $\square$ Certified copies of the priority documents ha	ave been received.			
2. Certified copies of the priority documents ha	ave been received in Application No			
application from the International Bu				
*See the attached detailed Office action for a list of t	the certified copies not received.			
14) Acknowledgement is made of a claim for domest	ic priority under 35 U.S.C. § 119(e).			
a) The translation of the foreign language provision				
15) Acknowledgement is made of a claim for domest	ic priority under 35 U.S.C. §§ 120 and/or 121.			
Attachment(s)				
1) X Notice of References Cited (PTO-892)	4) Interview Summary (PTO-413) Paper No(s).			
2) \( \text{Notice of Draftsperson's Patent Drawing Review (PTO-948)} \) 5) \( \text{Notice of Informal Patent Application (PTO-152)} \) 3) \( \text{X Information Disclosure Statement(s) (PTO-1449) Paper No(s).} \( \text{0803} \) 6) \( \text{X Other: Detailed Action} \)				
M Information Disclosure Statement(s) (PTO-1449) Paper No(s).	6) X Other: Detailed Action			

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**DETAILED ACTION** 

Claim Objections

1. Claims 1, 6 and 10 are objected to because of the following informalities: The word "identify" of claim 1 on line 5 should be changed to "identifying" and the word "MOLDI-TOF"

on claims 6 and 10 should be changed to "MALDI-TOF". Appropriate correction is required.

Claim 10 is also objected to because of the use of improper Markush group. "CNBr" is a chemical and does not belong to the genus claimed (which includes mass accuracy and molecular weight etc.). Appropriate correction is required by deleting "CNBr" from the Markush group.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Mazzara et al.

(U.S. Patent 5,747,324) (May 5, 1998).

Mazzara et al teach a method to identify the polypeptide correlating with a phenotype of interest, wherein the polypeptide specifically recognizes and binds a serum antibody, the method

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comprising identifying the polypeptide common to a list of characterized genes, wherein the genes are differentially expressed in one or more relevant cells or tissues and a list of characterized polypeptides, thereby identifying the polypeptide correlating with the phenotype of interest (Column 3, lines 14-57, Column 13, lines 23-42, and Example 6, Column 19, lines 1-35).

Mazzara et al teach a method, wherein the genes of the list are characterized by properties of the gene product, wherein the property is selected from specific reactivity with the serum antibody (Example 6, Column 19, lines 1-35).

Mazzara et al teach a method, wherein two or more properties characterize the properties of the gene product (Column 9, lines 24-39). Mazzara et al inherently teach a method, further comprising the property of molecular weight (Column 9, lines 24-39). This inherency is deduced from the fact that Western blot analysis of Mazzara et al., automatically provides molecular weight property of the expressed antigen because it is well known in the art that a standard mixture of proteins with known molecular weight is always run on gel by any ordinary practitioner to compare with the target polypeptide of interest.

## Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being obvious over Mazzara et al. (U.S. Patent 5,747,324) (May 5, 1998) in view of Greenspan (U.S. Patent 6,551,575 B1) (April 22, 2003).

Mazzara et al teach a method of claims 1-9 as described above.

Mazzara et al do not teach a method, wherein MALDI-TOF selection criteria of expressed polypeptides is selected from molecular weight range and mass accuracy.

Greenspan teaches a method, wherein MALDI-TOF selection criteria of expressed polypeptides is selected from molecular weight range and mass accuracy (Column 16, lines 33-45).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the method, wherein MALDI-TOF selection criteria of expressed polypeptides is selected from molecular weight range and mass accuracy of

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Greenspan into the method of analyzing polypeptides (expressed gene product) of Mazzara et al, since Greenspan states, "Methods of detecting or quantitating protein expression include twodimensional gel electrophoresis, MALDI-TOF mass spectrometry, and ProteinChip/SELDI mass spectrometry technology (Column 16, lines 43-45)". An ordinary practitioner would have been motivated to combine and substitute the method, wherein MALDI-TOF selection criteria of expressed polypeptides is selected from molecular weight range and mass accuracy of Greenspan into the method of analyzing polypeptides (expressed gene product) of Mazzara et al., in order to achieve the express advantages, as noted by Greenspan, of MALDI-TOF mass spectrometry, and ProteinChip/SELDI mass spectrometry technology which provide methods of detecting or quantitating protein expression.

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## Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 746-4979. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group LIE Chantae Dessau whose telephone number is (703) 605-1237.

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Arun Chakrabarti,

Patent Examiner,

September 9, 2003

ARUNK. CHAKRABARTI
PATENT EXAMINER

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